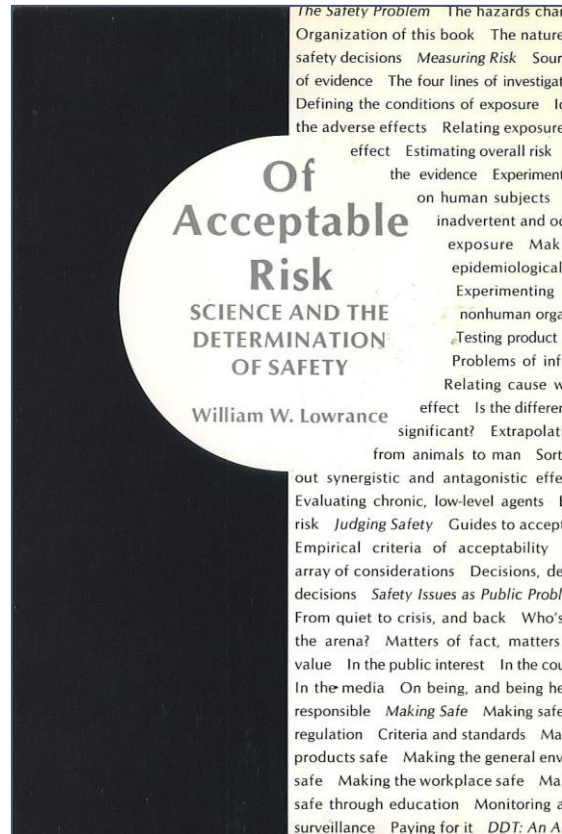


# Afternoon Session

# Of Acceptable Risk (Lowrance)



William Lowrance  
1977

*“A thing is safe if its risks are judged to be acceptable.”*

**Therefore**

- We need to have sufficiently certain estimates of risk
- And, we need to have a judgment on acceptability of risk.

# What health effects are of concern?

- To the public generally
- To policy-makers
- To parents
- To other groups

# What Is An “Adverse Effect”

## **1985 statement of the American Thoracic Society**

*“Guidelines as to what constitutes an adverse respiratory health effect, with special reference to epidemiological studies of air pollution”*

Medically significant physiologic or pathologic changes generally evidenced by one or more of the following:

- Interference with the normal activity of the affected person or persons
- Episodic respiratory illness
- Incapacitating illness
- Permanent respiratory injury and/or
- Progressive respiratory dysfunction

# What Is An “Adverse Effect”

## 2000 statement of the American Thoracic Society

### *“What Constitutes an Adverse Health Effect of Air Pollution?”*

- A. Increased mortality
- B. Increased incidence of cancer
- C. Increased frequency of symptomatic asthmatic attacks
- D. Increased incidence of lower respiratory tract infections
- E. Increased exacerbations of disease in persons with chronic cardiopulmonary or other disease that could be reflected in a variety of ways
  1. Less able to cope with daily activities (i.e., shortness of breath or increased anginal episodes)
  2. Increased hospitalization, both frequency and duration
  3. Increased emergency ward or physician visits
  4. Increased pulmonary medication
  5. Decreased pulmonary function
- F. Reduction in FEV1 or FVC associated with clinical symptoms
  1. Chronic reduction in FEV1 or FVC associated with clinical symptoms
  2. A significant increase in number of persons with FEV1 below normal limits: chronically reduced FEV1 is a predictor of increased risk of mortality.
  3. An increased rate of decline in pulmonary function (FEV1) relative to the predicted value in adults with increasing age or failure of children to maintain their predicted FEV1 growth curve.
- G. Increased prevalence of wheezing in the chest apart from colds, or of wheezing most days or nights.
- H. Increased prevalence or incidence of chest tightness
- I. Increased prevalence or incidence of cough/phlegm production requiring medical attention
- J. Increased incidence of acute upper respiratory infections that interfere with normal activity
- K. Acute upper respiratory tract infections that do not interfere with normal activity
- L. Eye, nose, and throat irritation that may interfere with normal activity (i.e., driving a car) if severe
- M. Odors

# What Is An “Adverse Effect”

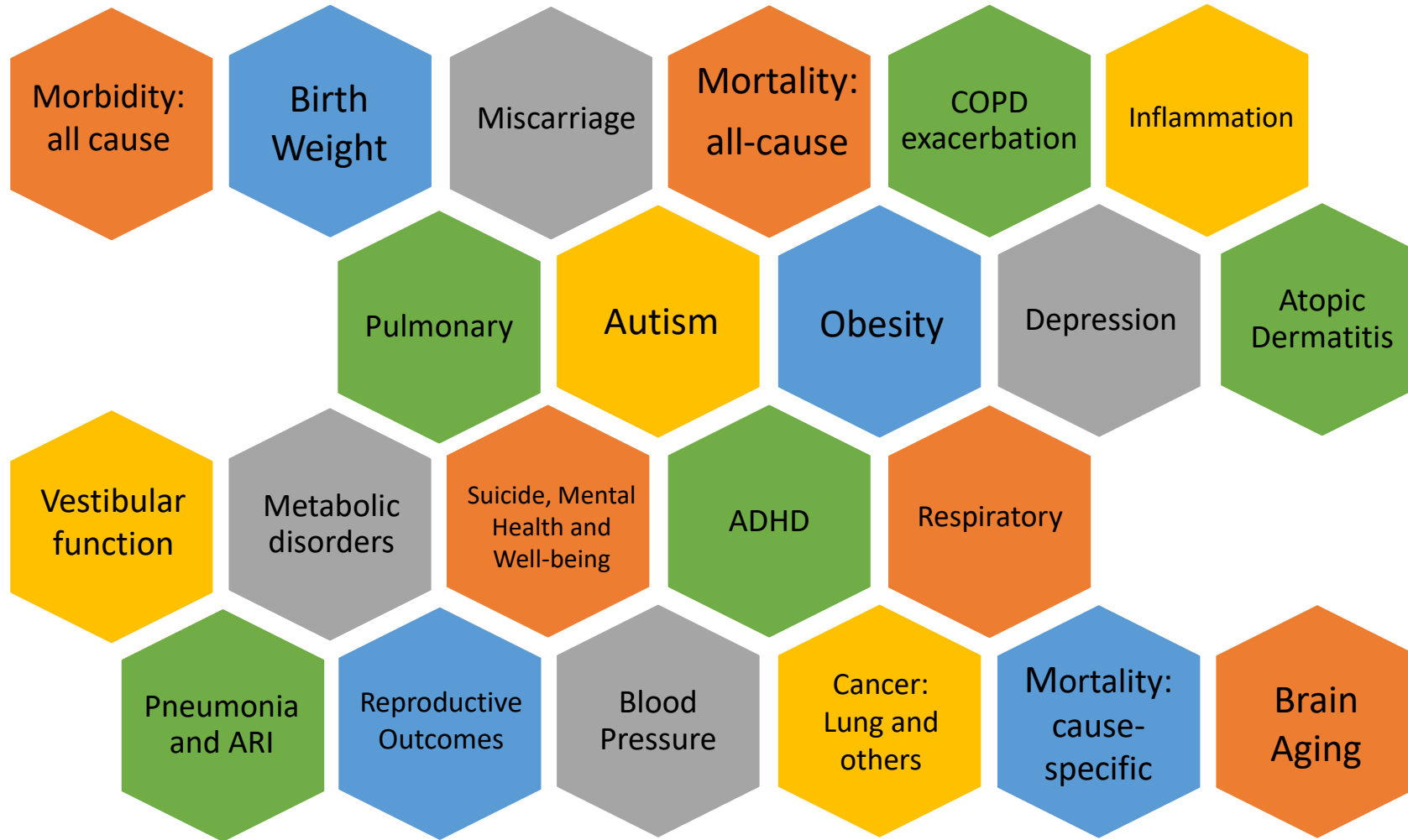
## 2017 statement of the American Thoracic Society

*“A joint ERS/ATS policy statement: what constitutes an adverse health effect of air pollution? An analytical framework”*

TABLE 1 Considerations for assessing adversity of clinical or pathological effects

| Consideration                             | Pertinent questions   |
|---|---|
| <b>1. Fatality</b>                        | Does air pollution exposure lead to an increase of short-term or long-term mortality?   |
| <b>2. Persistence of effect</b>           | How persistent over time is the effect? (Generally, chronic effects such as the induction of new disease are given greater weight, although short-term exposures may lead to changes that increase risk for triggering acute adverse events, such as myocardial infarction) |
| <b>3. Population risk</b>                 | Is there a shift in the population risk distribution of an adverse event?   |
| <b>4. Susceptibility</b>                  | Are the very young, older adults or individuals with pre-existing health conditions or specific genetic characteristics more likely to be affected?   |
| <b>5. Medical/functional significance</b> | Is there evidence of one or more of the following? 1) severe interference with a normal activity of the affected person or persons; 2) incapacitating illness; 3) permanent injury; 4) progressive dysfunction; 5) reduced quality of life                                  |

# Adverse Effects



# Emerging Risks



## THE POLLUTED BRAIN

The microscopic particles sifting from freeways and power plants don't just harm your heart and lungs. They may also attack your brain

By Emily Underwood, in Los Angeles, California

In a barbed wire-enclosed parking lot 100 meters downwind of the Route 110 freeway, an aluminum hose sticks out of a white trailer, its nozzle aimed at an overpass. Every minute, the hose sucks up hundreds of liters of air mixed with exhaust from the roughly 300,000 cars and diesel-burning freight trucks that rumble by each day.

Crouched inside the trailer, a young chemical engineer named Arian Saffari lifts the lid off a sooty cylinder attached to the hose, part of a sophisticated filtration system that captures and sorts pollutants by size. Inside is a scientific payload: particles of sulfate, nitrate, ammonium, black carbon, and heavy metal at least 200 times smaller than the width of a human hair.

The particles are too fine for many air pollution sensors to accurately measure,

says Saffari, who works in a lab led by Constantinou Sioutas at the University of Southern California (USC) here. Typically smaller than 0.2  $\mu\text{m}$  in diameter, these "ultrafine" particles fall within a broader class of air pollutants commonly referred to as PM<sub>2.5</sub> because of their size, 2.5  $\mu\text{m}$  or less. When it comes to toxicity, size matters: The smaller the particles that cells are exposed to, Saffari says, the higher their levels of oxidative stress, marked by the production of chemically reactive molecules such as peroxides, which can damage DNA and other cellular structures.

Some of the health risks of inhaling fine and ultrafine particles are well-established, such as asthma, lung cancer, and, most recently, heart disease. But a growing body of evidence suggests that exposure can also harm the brain, accelerating cognitive aging, and may even increase risk of Alzheimer's

disease and other forms of dementia.

The link between air pollution and dementia remains controversial—even its proponents warn that more research is needed to confirm a causal connection and work out just how the particles might enter the brain and make mischief there. But a growing number of epidemiological studies from around the world, new findings from animal models and human brain imaging studies, and increasingly sophisticated techniques for modeling PM<sub>2.5</sub> exposures have raised alarms. Indeed, in an 11-year epidemiological study to be published next week in *Translational Psychiatry*, USC researchers will report that living in places with PM<sub>2.5</sub> exposures higher than the Environmental Protection Agency's (EPA's) standard of 12  $\mu\text{g}/\text{m}^3$  nearly doubled dementia risk in older women. If the finding holds up in the general population, air pollu-

PHOTO: GETTY IMAGES/SCIENCE SOURCE/SCIENCEMAG.ORG ON JANUARY 26, 2017

PHOTO: GETTY IMAGES/SCIENCE SOURCE/SCIENCEMAG.ORG

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# Emerging Risks

- Reproductive outcomes
  - Birth weight
  - Neuropsychological development
  - Neuropsychological disorders (autism)
- "Brain aging"
  - Increased cognitive decline
  - Alzheimer's Disease
- Welfare effects
  - Mood
  - Suicide risk

# Explaining and using the findings

- Technical details
  - Exposure measures
  - Measures used—HRs and ORs
  - Dose-response functions
  - Uncertainty
- What is adverse
- Disease burden estimates
- Causation (or not)

## The “new tobacco”?



▲ Dr Tedros Adhanom Ghebreyesus speaks at a press conference in 2017. Photograph: Fabrice Coffrini/AFP/Getty Images

Air pollution is the “new tobacco”, the head of the **World Health Organization** has warned, saying the simple act of breathing is killing 7 million people a year and harming billions more.

# The Clean Air Act



Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one *“the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, is requisite to protect the public health.”*

**NAAQS= National Ambient Air Quality Standard**

# The NAAQS: From Evidence to Standards

